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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,331	11/09/2001	James C. Paulson	019957-011211US	3312
20350	7590 04/22/2003			
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR			EXAMINER	
			RAO, MANJUNATH N	
	ISCO, CA 94111-3834	L		
DIN TIGHT	,00,011 74111 5054		ART UNIT	PAPER NUMBER
			1652	()
			DATE MAILED: 04/22/2003	φ

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
: · ·	10/007,331	PAULSON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Manjunath N. Rao, Ph.D.	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute,	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
 Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status 	date of this communication, even if timely filed	, may reduce any				
1)⊠ Responsive to communication(s) filed on 18 J	<u>une 2002</u> .					
_	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	P. J. O. and Parkara					
4) Claim(s) <u>12-20,23-31,44-53 and 55-102</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
,	7) Claim(s) is/are objected to.					
8)⊠ Claim(s) <u>12-20,23-31,44-53 and 55-102</u> are subject to restriction and/or election requirement. Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120	•					
13) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a	a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents	s have been received in Applicati	on No				
Copies of the certified copies of the prior application from the International But * See the attached detailed Office action for a list.	reau (PCT Rule 17.2(a)).					
14) Acknowledgment is made of a claim for domesti	·					
a) The translation of the foreign language pro	visional application has been rec	eived.				
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal I	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 12-20, 23-31-31, 44-53, 55-58, 59-81, 98-101 drawn to commercial scale method of or an *in vitro* method of sialylation using bacterial or recombinant bacterial enzymes, classified in class 435, subclass 97.
- II. Claims 82-92, and 102, drawn to an *in vitro* commercial method of altering the glycosylation pattern of a glycoprotein by transfer of galactose from a UDP-galactose to a saccharide to form a galactosylated saccharide, classified in class 435, subclass 15.
- III. Claims 93-97, drawn to composition comprising a glycoprotein, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II are patentably distinct from each other. The method of *in vitro* or commercial scale sialylation of a glycoprotein of group I, the *in vitro* or commercial scale method of glycosylating a protein of group II are unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions I, II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the sialylated and glycosylated proteins can be made by isolating them from their sources as opposed to the methods of groups I and II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

MANJUNATH RAO PATENT EXAMINER

Manjunath N. Rao April 8, 2003